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Prevention of Inappropriate Therapy in Implantable Cardioverter-Defibrillators

Results of a Prospective, Randomized Study of Tachyarrhythmia Detection Algorithms

Dominic A. M. J. Theuns, MSc,* A. Peter J. Klootwijk, MD, PhD,* Dick M. Goedhart, MSc,† Luc J. L. M. Jordaens, MD, PhD*

Rotterdam, the Netherlands

OBJECTIVES The purpose of this randomized study was to investigate the performance of single- and dual-chamber tachyarrhythmia detection algorithms.

BACKGROUND A proposed benefit of dual-chamber implantable cardioverter-defibrillators (ICDs) is improved specificity of tachyarrhythmia detection.

METHODS All ICD candidates received a dual-chamber ICD and were randomized to programmed single- or dual-chamber detection. Of 60 patients (47 male, age 58 ± 14 years, left ventricular ejection fraction 30%), 29 had single-chamber and 31 had dual-chamber settings. The detection results were corrected for multiple episodes within a patient with the generalized estimating equations method.

RESULTS A total of 653 spontaneous arrhythmia episodes (39 patients) were classified by the investigators; 391 episodes were ventricular tachyarrhythmia (32 patients). All episodes of ventricular tachyarrhythmias were appropriately detected in both settings. In 25 patients, 262 episodes of atrial tachyarrhythmias were recorded. Detection was inappropriate for 109 atrial tachyarrhythmia episodes (42%, 18 patients). Rejection of atrial tachyarrhythmias was not significantly different between both groups ($p = 0.55$). Episodes of atrial flutter/tachycardia were significantly more misclassified ($p = 0.001$). Overall, no significant difference in tachyarrhythmia detection (atrial and ventricular) between both settings was demonstrated ($p = 0.77$).

CONCLUSIONS The applied detection criteria in dual-chamber devices do not offer benefits in the rejection of atrial tachyarrhythmias. Discrimination of atrial tachyarrhythmias with a stable atrioventricular relationship remains a challenge. (J Am Coll Cardiol 2004;44:2362–7) © 2004 by the American College of Cardiology Foundation

Despite the proven benefit from advancing implantable cardioverter-defibrillator (ICD) technology, a substantial proportion of ICD recipients experience inappropriate ICD therapy due to atrial tachyarrhythmias (1–5). In patients with a single-chamber device, inappropriate classification of atrial tachyarrhythmias occurs in approximately 20% to 30% of patients (1,6,7). The development of dual-chamber devices provides the opportunity to improve the accuracy of tachyarrhythmia detection by the addition of atrial information (8,9). The superiority of detection algorithms in dual-chamber ICDs has not been proven so far. Prospective, randomized studies evaluating the efficacy of dual-chamber detection algorithms are lacking. The advantages of dual-chamber ICDs for accurate discrimination are small or even nonexistent (10,11). Even more, dual-chamber pacing offers no clinical advantage over ventricular backup pacing in ICD patients with no indication for cardiac pacing (12).

We designed a prospective, randomized study to compare the performance of tachyarrhythmia detection algorithms in single-chamber and dual-chamber ICDs.

METHODS

Study design. The Prevention of Inappropriate (PINAPP) therapy study was a single-center, prospective, randomized study of patients comparing single- and dual-chamber discrimination criteria. All patients had a standard indication for ICD implantation for the treatment of ventricular tachyarrhythmias but without an indication for antibradycardia pacing. Patients with permanent atrial fibrillation (AF) or an indication for resynchronization therapy were excluded from the trial. The clinical characteristics of the patients are summarized in Table 1.

The local ethical committee approved the study. Written informed consent was obtained from all patients before study enrollment. All patients received a dual-chamber device. The patients were randomly assigned to have the device programmed to single-chamber supraventricular detection algorithms (SC group) or to the enhanced dual-chamber supraventricular detection algorithms (DC group). Random assignment was obtained by telephone to an independent service (Cardialysis, Rotterdam, the Netherlands).

From the *Department of Cardiology, Thoraxcenter, Erasmus MC, Rotterdam, the Netherlands; and the †Department of Statistics, Cardialysis, Rotterdam, the Netherlands. Supported by research grants from Biotronik (the Netherlands) and Guidant (the Netherlands).

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Abbreviations and Acronyms

AF = atrial fibrillation
AFL = atrial flutter
AT = atrial tachycardia
DC group = dual-chamber supraventricular detection algorithm group
GEE = generalized estimating equation
ICD = implantable cardioverter-defibrillator
SC group = single-chamber supraventricular detection algorithm group
ST = sinus tachycardia

Device description. The devices implanted in this study were, in equal numbers and randomized order, the Prizm DR (Guidant Corp., St. Paul, Minnesota) and the Tachos DR (Biotronik, Berlin, Germany). The pulse generator and endocardial leads were inserted through a single left pectoral incision. The endocardial lead used for the high right atrium was a bipolar active-fixation lead with an interelectrode spacing of 8.9 mm (Model 5076, Medtronic Inc., Minneapolis, Minnesota). Far-field R-wave sensing in the atrial electrogram was excluded. If present, the atrial lead was relocated until appropriate sensing could be achieved.

Discrimination of tachyarrhythmias. In both the SC group and DC group, the onset and stability criteria are provided to inhibit therapy in case of an atrial arrhythmia. In addition, dual-chamber devices have "enhanced discrimination" criteria to differentiate atrial from ventricular arrhythmias. In the Prizm DR, enhanced criteria are: 1) the "ventricular rate > atrial rate" criterion, and 2) the "AF rate threshold" criterion. When the ventricular rate > atrial rate (V > A) is programmed, onset and stability are ignored, and therapy will be delivered. The AF rate threshold (Afib threshold) criterion is programmed in conjunction with stability. The aim of this feature is to suppress inappropriate therapy for fast ventricular rates secondary to AF or atrial flutter (AFL). If the ventricular rhythm is classified unstable and the atrial rate is higher than the programmed Afib threshold, therapy is withheld (13).

The Tachos DR employs the SMART algorithm (Biotronik) as enhanced discrimination. This algorithm is based on continuous analysis of the average atrial and ventricular rate and their atrioventricular relationship, which results in three rate-branches (VV < AA, VV > AA, and VV = AA). The features of this algorithm have been described in detail (14).

Programming the devices. Throughout the study, the devices were programmed similarly as often as possible to facilitate comparison between both groups (Table 2). For all patients, the tachyarrhythmia detection algorithms were activated immediately after implantation. The SC group was programmed to supraventricular tachycardia discrimination on the basis of ventricular rate combined with onset (15% to 16%) and stability (40 ms). For the DC group, tachyarrhythmia discrimination was programmed to onset (15% to 16%) and stability (40 ms), and all applicable enhanced algorithms were activated. Safety timers were not activated in both groups. The tachycardia detection zones were programmed to recognize fibrillation and either one or two tachycardia zones. The bradycardia support was programmed to VVI with a lower rate of 40/min for the SC group. The DC group was set to the DDI mode with a lower rate of 40/min. The storage of intracardiac electrograms was programmed to collect both atrial and ventricular bipolar electrograms and markers for all patients.

End points. The primary end point in the study was the deliverance of inappropriate therapy for atrial arrhythmias. Secondary end points were appropriate and inappropriate arrhythmia classification. All spontaneous episodes detected either as ventricular tachyarrhythmia or as atrial tachyarrhythmia with stored electrograms were retrieved from the device's memory. Two independent experienced physicians

Table 1. Patient's Clinical Characteristics (n = 160)

	SC Group (n = 29)	DC Group (n = 31)	p Value
Gender (M/F)	24/5	23/8	NS
Age (yrs)	57 ± 17	61 ± 10	NS
LVEF (%)	29 ± 11	31 ± 10	NS
History of atrial arrhythmias (n)	8	7	NS
Underlying cardiac disease (n)			
CAD	21	26	NS
CMP (dilated)	6	3	NS
CMP (hyperthropic)	2	2	NS
Presenting arrhythmia (n)			
VF	7	9	NS
SMVT	17	15	NS
NSVT + inducible VT/VF	5	7	NS
Pharmacologic treatment (n)			
Amiodarone	11	8	NS
Beta-blockers	17	17	NS
Digoxin	6	4	NS
No antiarrhythmic drug	7	7	NS
ACE inhibitor	21	26	NS
Diuretic	15	17	NS
Lipid-lowering drug	17	23	NS

ACE = angiotensin-converting enzyme; CAD = coronary artery disease; CMP = cardiomyopathy; DC group = dual-chamber supraventricular detection algorithm group; LVEF = left ventricular ejection fraction; NS = nonsignificant; NSVT = non-sustained ventricular tachycardia; SC group = single-chamber supraventricular detection algorithm group; SMVT = sustained monomorphic ventricular tachycardia; VF = ventricular fibrillation; VT = ventricular tachycardia.

Table 2. Programming of Detection Algorithms in the SC Group and DC Group

	SC Group		DC Group	
	Biotronik	Guidant	Biotronik	Guidant
Onset (%)	15	16	15	16
Stability (ms)	40	40	40	40
SMART	OFF	NA	ON	NA
V > A	NA	OFF	NA	ON
AF threshold	NA	OFF	NA	200/min

AF = atrial fibrillation; NA = not applicable; V > A = ventricular rate > atrial rate; other abbreviations as in Table 1.

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analyzed the stored episodes to assess the type of the clinical arrhythmia and the appropriateness of device classification. In case of doubt, a third physician was consulted to provide the decision. The stored arrhythmias were classified as: 1) ventricular arrhythmia, or 2) atrial arrhythmia without a co-existent ventricular arrhythmia. The atrial arrhythmias were further classified as AF, AFL, atrial tachycardia (AT), and sinus tachycardia (ST). Atrial fibrillation was assumed to occur if the atrial electrogram showed a changing morphology. The diagnosis of AFL was based on regular AA intervals and no changes in morphology of the atrial electrogram. The prerequisite of ST and AT was an atrial electrogram preceding the ventricular electrogram. Sinus tachycardia was diagnosed if the ventricular rhythm showed a gradual increase in heart rate with an unchanged morphology of the atrial and ventricular electrogram. In contrast, the diagnosis of AT was based on a sudden increase of the ventricular rate and a change in morphology of the atrial electrogram.

Statistical analysis. Based on the assumption of a 30% reduction in the incidence of inappropriate therapy with dual-chamber devices, 27 patients were required in each, for a power of 80% and a probability value of 0.05.

Continuous variables were expressed as mean values ± SD. Chi-square testing was used for analysis of categorical variables, and the Student *t* test was used for analysis of continuous variables. A p value <0.05 was considered statistically significant.

The set of tachyarrhythmia episodes cannot be considered as independent because patients contribute one or more tachyarrhythmia episodes to the dataset. To correct for these factors, statistical analysis was performed by using the generalized estimating equations (GEE) statistical method with an exchangeable correlation structure to correct the varying number of episodes that were obtained from each patient (15,16). Only episodes with a stored electrogram and the physician's classification were included in the analysis. Statistical analysis was performed with SPSS for Windows (release 10.1, SPSS Inc., Chicago, Illinois) and SAS for Windows (release 8.2, SAS Institute, Cary, North Carolina).

Calculations were based on the possibility to accurately detect ventricular arrhythmias (true positive [TP]), accurately detect atrial arrhythmias (true negative [TN]), falsely detect atrial arrhythmias as ventricular (false positive [FP]), and falsely detect ventricular arrhythmias as atrial (false negative [FN]). The sensitivity of detection algorithms is the probability that a ventricular arrhythmia is detected when present: [TP/(FN + TP)]. The specificity of detection algorithms is the ability to reject atrial tachyarrhythmias. An absolute specificity cannot be calculated. The specificity is dependent on the prevalence of atrial tachyarrhythmias and the programmed detection interval of the device. Therefore, we calculated the positive predictive value of the detection algorithm as follows: [TP /(TP + FP)].

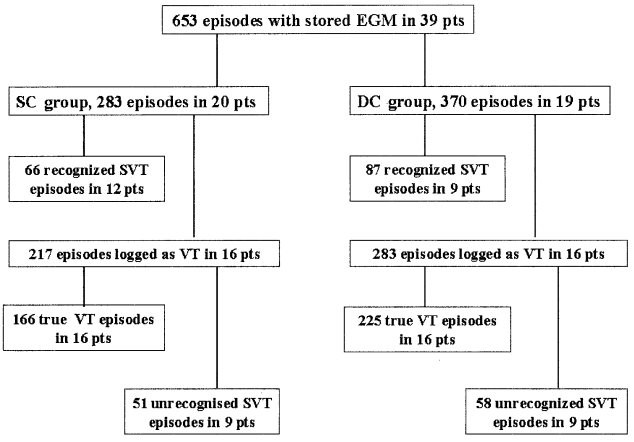

Figure 1. Tree diagram showing the results for 653 stored spontaneous tachyarrhythmia episodes. DC group = dual-chamber supraventricular detection algorithm group; EGM = electrogram; pts = patients; SC group = single-chamber supraventricular detection algorithm group; SVT = supraventricular tachyarrhythmias; VT = ventricular tachycardia.

RESULTS

Patient population. Sixty patients were included in the study. A total of 29 patients were randomly assigned to the SC group and 31 to the DC group. Fifteen patients in the SC group were randomized to Biotronik and 14 patients to Guidant. In the DC group, 14 patients were randomized to Biotronik and 17 patients to Guidant. Baseline clinical characteristics did not differ between the two groups (Table 1). At the time of implantation, all patients had sinus rhythm. A history of atrial tachyarrhythmias was documented in 15 patients (25%), paroxysmal AF in 11 patients (18%), and paroxysmal AFL in 2 patients (3%). Pharmacologic treatment at discharge was not significantly different between the two groups. Antiarrhythmic drug therapy was amiodarone in 19 patients (32%), beta-blockade in 34 patients (57%), and 10 patients (17%) received digoxin.

Five patients (8%) had two tachycardia zones activated. In four of these patients, the programmed detection criteria were applicable to both tachycardia zones. The programmed fibrillation and tachycardia zones were 290 ± 14 ms and 387 ± 34 ms, respectively. The programmed tachycardia detection interval was not significantly different between the two groups (SC group, 379 ± 31 ms vs. DC group, 389 ± 35 ms).

Spontaneous tachyarrhythmias. The mean follow-up was 12 months, with a cumulative follow-up of 717 months. During this follow-up, 653 tachyarrhythmia episodes with stored electrogram occurred in 39 patients (range 1 to 89 episodes per patient). Figure 1 presents a tree diagram that outlines the results of arrhythmia detection for each of the 653 stored tachyarrhythmia episodes. Based on the physician classification, there were a total of 391 episodes of true ventricular tachyarrhythmias in 32 patients (mean ventricular rate 358 ± 77 ms). In 25 patients, 262 episodes of true atrial tachyarrhythmias (mean ventricular rate 368 ± 32 ms) occurred. In Figure 2, the number of episodes for the two

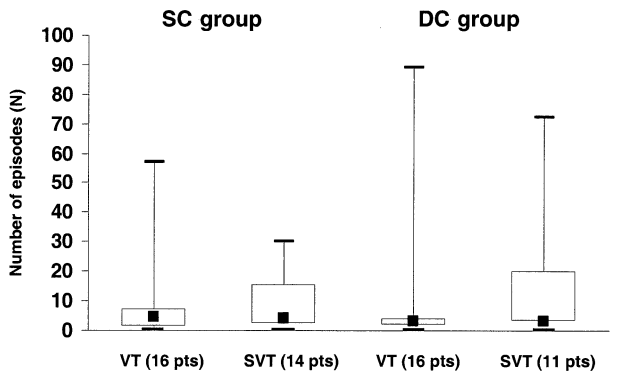

Figure 2. Number of spontaneous episodes per patient for the two study groups. The **error bars** extend down to the minimum value and up to the maximum value. The **box** extends from the 25th percentile to the 75th percentile, with a **black box** at the median (50th percentile). Abbreviations as in Figure 1.

study groups is presented. In the SC group, 166 episodes of ventricular tachyarrhythmias were recorded in 16 patients (range 1 to 57 episodes per patient); in the DC group, 225 episodes in 16 patients (range 1 to 89 episodes per patient). All ventricular tachyarrhythmias were appropriately detected in both groups. The sensitivity for ventricular tachyarrhythmias in both groups was 100%.

Of the 262 atrial tachyarrhythmia episodes in the ventricular tachyarrhythmia detection window, 153 (58%) were detected as atrial tachyarrhythmia and not as ventricular tachyarrhythmia (20 patients). Inappropriate detection was observed in 109 atrial tachyarrhythmia episodes (18 patients). The mean ventricular rate of misclassified atrial tachyarrhythmias was significantly shorter compared with rejected atrial tachyarrhythmias (354 ± 30 ms vs. 378 ± 30 ms; $p < 0.001$). The number of misclassified episodes was not significantly different between the two groups (51 in the SC group vs. 58 in the DC group). Analysis performed with the GEE method demonstrated no significant difference in the rejection of spontaneous atrial tachyarrhythmias between single- and dual-chamber devices ($p = 0.56$). The detection of ventricular tachyarrhythmias and the rejection of atrial tachyarrhythmias was not significantly different between the two groups ($p = 0.77$). The specificity and positive predictive value of arrhythmia discrimination were 56% and 76% in the SC group, versus 60% and 79% in DC group, respectively.

During 60 atrial tachyarrhythmia episodes (13 patients), inappropriate device therapy was delivered. The number of inappropriately treated episodes was not significantly different between the two groups (28 in the SC group vs. 32 in the DC group).

Subanalysis of atrial tachyarrhytmias. The misclassified atrial tachyarrhythmias are presented in Table 3. Subanalysis of the type of atrial arrhythmia and the appropriateness of classification was performed with the GEE method. Analysis demonstrated a significantly higher misclassification in case of AFL/AT compared with ST and AF ($p = 0.001$). The misclassified episodes of AT/AFL had a sudden onset >16% and a regular ventricular response (stability <40 ms). Episodes of ST were misclassified due to the presence of ventricular premature beats that resulted in false sudden-onset calculations or false V > A detection in dual-chamber devices.

Table 3. Inappropriate Classification of Spontaneous Atrial Tachyarrhythmias for Both Groups

		Misclassified Episodes		
Arrhythmia	(n)	SC Group (%)	DC Group (%)	p Value
Atrial fibrillation	89	38 (2 patients)	26 (4 patients)	NS
Atrial flutter	30	47 (1 patient)	50 (1 patient)	NS
Atrial tachycardia	63	97 (6 patients)	96 (5 patients)	NS
Sinus tachycardia	80	5 (1 patient)	18 (2 patients)	NS

Abbreviations as in Table 1.

DISCUSSION

The present prospective, randomized study evaluated the performance of tachyarrhythmia detection algorithms in single-chamber and dual-chamber ICDs. Although identical programmed stability and onset values were used, the number of inappropriate classifications with dual-chamber detection was not significantly reduced compared with single-chamber detection.

Inappropriate ICD therapy for atrial tachyarrhythmias is the most common adverse event in ICD recipients with single-chamber devices (17). With the development of dual-chamber cardioverter-defibrillators, it was anticipated that these devices could improve arrhythmia detection by providing additional information about the underlying atrial rhythm. In previous studies, enhanced detection algorithms in dual-chamber devices based on the atrioventricular relationship could accurately discriminate atrial from ventricular tachyarrhythmias (8,9). However, most of the studies were restricted to one manufacturer and mainly focused on the technical performance of the implanted device (8,14,18–20). Prospective, randomized studies to evaluate the efficacy of enhanced detection algorithms to decrease the incidence of inappropriate therapies are lacking in a well-defined population.

Accuracy of tachyarrhythmia detection. The primary goal of the ICD is to detect and subsequently terminate life-threatening ventricular tachyarrhythmias. When evaluating tachyarrhythmia detection criteria in our study, the sensitivity for detection of ventricular tachyarrhythmias was 100% for both study groups. Single-chamber and dual-chamber ICDs were equally safe and effective in treating ventricular tachyarrhythmias. This is in agreement with other device trials (8,10,11,14,18,19).

The secondary goal of the ICD is to deliver therapy only when required. Thus, accurate discrimination between atrial and ventricular tachyarrhythmias is an important clinical issue. The overall incidence of inaccurately detected tachyarrhythmias by the device was 16.7%. This finding is in

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agreement with studies reporting on inappropriate ICD therapy (21,22). We found no significant difference in the number of misclassified episodes between both groups (51 episodes, SC group vs. 58 episodes, DC group). The results in our study demonstrated that enhanced detection criteria in single-chamber and dual-chamber ICDs are equally effective in the rejection of atrial tachyarrhythmias. This finding is confirmed by previous comparisons of enhanced detection criteria between single- and dual-chamber ICDs (10,11). These investigators reported no reduction or even an excess of inappropriate ICD therapies in dual-chamber devices. The failure of detection enhancements in dual-chamber devices to withhold therapy for atrial tachyarrhythmias was attributed by the investigators to atrial sensing problems. Inappropriate classification of atrial tachyarrhythmias due to atrial sensing problems was also reported in other studies (19,23).

Limitations of the applied enhanced detection criteria. The strength and weakness of enhanced detection criteria are dependent on the frequency and distribution of atrial tachyarrhythmias. The complete picture of the performance of detection criteria is provided not only by statistical measures. The picture is complemented with observations during misclassified atrial tachyarrhythmias. The observed weaknesses of the applied detection criteria to discriminate between atrial and ventricular tachyarrhythmias were the presence of: 1) atrial tachyarrhythmias with stable N:1 atrioventricular conduction; and 2) ST with the presence of ventricular premature beats.

ATRIAL TACHYARRHYTHMIAS WITH STABLE ATRIOVENTRICULAR CONDUCTION. In both settings, detection was inappropriate in the majority of atrial tachyarrhythmias with a fixed N:1 atrioventricular conduction (AT and AFL). In single-chamber setting, the sudden-onset (onset $\geq$16%) and the stable ventricular response (stability $<$40 ms) fulfilled ventricular tachyarrhythmia detection. Given the priority of single-chamber detection criteria, the additional dual-chamber detection enhancement "Afib threshold" cannot decrease the incidence of inappropriate detections for atrial tachyarrhythmias with stable N:1 atrioventricular conduction. A recent study confirmed the high incidence of inappropriate classification of ATs with stable 1:1 atrioventricular conduction (24).

Dual-chamber algorithms analyzing the atrioventricular conduction have the possibility to detect stable atrial tachyarrhythmias with N:1 atrioventricular conduction. Despite the use of the dual-chamber algorithm SMART, a variation in the calculated mean atrial rates led to inappropriate therapy in 2:1 conducted AFL. A progressively prolonging atrioventricular conduction interval can be misclassified as ventricular tachycardia with retrograde conduction. This problem has been reported as the most common failure of the PR Logic algorithm (Medtronic Inc.) (19,25).

ST. In case of ventricular premature beats during ST, the dual-chamber detection enhancement "V $>$ A" can act as an accelerator of inappropriate detection. During a ventricular premature beat, the normal atrial activation might be not sensed due to the atrial blanking period after a sensed ventricular event, which fulfills the detection enhancement "V $>$ A." Another problem associated with premature ventricular beats is the inappropriate calculation of a sudden onset. This problem has also been reported in previous studies (26,27).

Comparison with other studies. A comparison of the performance of the applied detection criteria with other studies is difficult because the applied detection criteria, the number of episodes, the number of patients, and the methodology differ between the published studies. In an open-label nonrandomized study comparing single- and dual-chamber devices, the incidence of inappropriate therapies during AF was significantly higher in dual-chamber devices compared with single-chamber devices (41% vs. 24%) (10). In a recent prospective, randomized study between single- and dual-chamber devices, no differences in performance of detection criteria were observed (11). However, the results must be interpreted with caution, because all inappropriate therapies, including those in the ventricular fibrillation zone and those not related to atrial tachyarrhythmias, were considered in the study by Deisenhofer et al. (11).

Studies with dual-chamber ICDs have reported high sensitivity and specificity values for the applied dual-chamber algorithm. In a recent study with the PARAD algorithm (ELA Medical, Le Plessis Robinson, France), a specificity of 89.2% on a per episode basis and 91.6% on a per patient basis were reported (20). Despite the high overall specificity, the performance during AF was poor (47.2% of 53 episodes were inappropriately detected). Studies evaluating the PR Logic algorithm reported lower specificity values of 66.6% or 72% on a per episode basis (19,25). For Guidant devices, the performance of "Afib threshold" and "V $>$ A" in conjunction with a more aggressively programmed onset (9%) and stability (24 ms) was recently reported with a specificity of 89% (24).

Limitations of the study. We used devices from only two manufacturers to assess the accuracy of atrial tachyarrhythmia detection in single- and dual-chamber ICDs. The results of our study must, therefore, be interpreted with caution. The findings of the study do not reflect the status of current detection algorithms in general. Current devices can apply morphology discrimination in conjunction with timing-based detection algorithms. The present study evaluated only timing-based detection algorithms. The predefined programming of the onset (16%) and stability criterion (40 ms) in the Guidant dual-chamber devices potentially reduced the potential advantage of the enhancement criteria ("V $>$ A" and "Afib threshold") (24). A more aggressive onset and stability will first cause a loss in sensitivity but an increase in specificity.

"V $>$ A" will compensate the loss in sensitivity. As our study demonstrated that not ST nor AF but AT and AFL with a fixed N:1 conduction were the problem, it is very unlikely that lower stability values would have changed the

results. Another possible limitation is the number of patients. However, 653 episodes of tachyarrhythmias were analyzed. The programmed detection rate affects both the distribution of the type of atrial tachyarrhythmias as well as the relative number of atrial tachyarrhythmias presenting to the detection algorithms. In our study, the programmed detection rate was similar for both groups.

Conclusions. In this study, using stored atrial electrograms from dual-chamber devices, the applied detection criteria in single- and dual-chamber setting were equally effective for detection of ventricular tachyarrhythmias and the rejection of atrial tachyarrhythmias. This was true for this study group without a bradycardia indication. Both subgroups were comparable in terms of underlying heart disease, indication for implantation, antiarrhythmic drug therapy, and follow-up period. This has important repercussions on health care in general, as in recent ICD trials, hospital readmissions due to new or worsened heart failure increased (5,12). This higher incidence was related to dual-chamber bradycardia pacing in patients without a bradycardia pacing indication. With the increasing indications for ICD implantation, a matter of debate is the device selection. The rules for device selection for patients with a primary prevention indication can be different from those applied for patients with a secondary prevention indication. Nevertheless, to avoid inappropriate therapy, it is particularly important to program carefully the enhanced detection criteria of the device, irrespective of the indication. Further work should be done to improve arrhythmia discrimination, in particular for atrial tachyarrhythmias with stable atrioventricular conduction, which was most often misclassified.

Reprint requests and correspondence: Dr. Luc Jordaens, Department of Clinical Electrophysiology, Bd402, Erasmus MC, Dr. Molewaterplein 40, 3015 GD Rotterdam, the Netherlands. E-mail: l.jordaens@erasmusmc.nl.

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